

REMARKS

Claims 24 and 65-77 are pending. Claims 68 and 71-77 are amended.

ISSUES PENDING

- The Specification is objected to for incomplete correspondence between the Figure descriptions and the Figure contents for Figures 7-9, 12, 14 and 18-20.
- Claims 71-77 are objected to for non-italicized genus names.
- Claims 67 and 71 are rejected under 35 U.S.C. 112 ¶ 2 as indefinite for the use of fungal versus yeast.
- Claims 24 and 65 are rejected under the judicially created obviousness-type double patenting doctrine over claims 1-2 of US Patent 6,635,447.
- Claims 24 and 65-77 are rejected under 35 U.S.C. 112 ¶ 1 as lacking adequate written description and for not having disclosure enabling for the breadth of the claims.

I. OBJECTIONS

1. The Specification is objected to for incomplete correspondence between the Figure descriptions and the Figure contents for Figures 7-9, 12, 14 and 18-20.

Applicant addressed the Examiner's objections by way of the Preliminary Amendment filed 07-15-2003. Applicant will be happy to submit a substitute specification at the Examiner's request.

2. Claims 71-77 are objected to for non-italicized genus names.

Applicant has amended the claims to italicize *Aspergillus* and other genus names.

II. 35 U.S.C. 112 ¶ 2

- 1.** Claims 67 and 71 are rejected under 35 U.S.C. 112 ¶ 2 as indefinite for the use of fungal versus yeast.

Applicant believes one of skill in the art would not be confused by the claims' use of yeast and fungal. However to advance prosecution, Applicant has amended claim 68. Applicant believes any remote possibility of confusion is eliminated by this amendment.

III. DOUBLE PATENTING

Applicant submits a terminal disclaimer to obviate the outstanding rejection over US Patent 6,635,447.

IV. 35 U.S.C. 112 ¶ 1

Written Description

Claim 24 is drawn to a process for producing human lactoferrin. The Applicant is not claiming human lactoferrin. Thus, the written description inquiry is properly framed as whether the Specification conveys to one of skill in the art that the inventors possessed at the time of filing a process for producing human lactoferrin comprising the listed steps. Written description is found in the disclosure and the original claim set. Applicant submits that the working examples and the general disclosure amply demonstrate possession of the claimed method.

With regard to the polynucleotide used in the claimed process, the Examiner's rejection is misplaced. The nucleic acid is not described with regard to its function of encoding human lactoferrin. Rather, "codes for a human lactoferrin protein" refers to a genus of polynucleotide sequences containing an open reading frame that, if translated, would produce human lactoferrin. This is a structural recitation common in the art and in patent

claiming. See, *e.g.*, US Pat. 6,635,447. In addition, the Examiner appears to be requiring a structural recitation to be within the claims. The original filed claims form part of the written description. But the bulk of the written description is in the disclosure. This written description is what is judged for sufficiency. There is no basis in the law for the position that written description in the disclosure cannot support a claim because one cannot import limitations from the disclosure into a claim. Office Action 05-01-06, pg. 12. The Examiner's argument confuses claim construction with written description sufficiency.

In general, the Examiner's position regarding written description for the pending claims is premised on a widely held misinterpretation of the law:

- (1) Examples are not necessary to support the adequacy of a written description,
- (2) the written description standard may be met even where actual reduction to practice of an invention is absent; and
- (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Falkner v. Inglis, 05-1324, (Interference No. 105,187), 2006 U.S. App. LEXIS 13127 (Fed. Cir. May 26, 2006).

For example, the Examiner rejects claims 65-66 and 69-70 for the lack of specific "empirical evidence," *i.e.* examples. Office Action 05-01-06, pg. 4. The Examiner applies a *per se* rule requiring evidence of reduction to practice. This is clearly improper.

Another example is the rejection of claim 24. The Examiner rejects the claim because "there is no indication of which nucleic acid encodes the protein." Again the Examiner applies an incorrect *per se* rule that a claim directed to "a biological macromolecule must contain a recitation of known structure."

Erroneously applying *per se* rules, mixing claim construction with adequacy of written description and miss-focusing the inquiry as one for a composition claim rather than a

method claim has led the Examiner to incorrect conclusions as to sufficiency of the written description.

Enablement

The pending claims relate to a process for producing human lactoferrin. The Examiner rejects the pending claims as enabled for only SEQ ID NO: 1. Office Action 05-01-06, pg. 6. Applicant contends there is adequate disclosure to enable the claimed process. The Examiner makes no reasoned argument why the working examples and general disclosure do not enable the claimed process. Instead, the Examiner confuses the issue by treating the claims as composition claims directed at human Lactoferrins. It is the Examiner's burden is to explain why the pending specification does not enable the claimed process for producing human lactoferrin. Applicant contends there is no technical basis upon which the Examiner can make such an argument.

The other grounds for rejection is the breadth of the cell types enabled by the specification. Office Action 05-01-06, pg. 6-7. Specifically, it appears the Examiner's rejection is that the examples and general guidance provided in the Specification do not enable the genus of processes encompassing use of eukaryotic cells or the sub-genera of processes using mammalian or insect cells. The Examiner then discusses how recombinant expression of human proteins in hamster kidney cells (mammalian) and insect cells is known in the art. The Specification further discloses several fungal based working examples.

"All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a 'reasonable correlation' to the scope of the claims." MPEP 2164.08. Applicant contends that the disclosure and working examples in view of the level of knowledge and skill in the art, as discussed by the Examiner and demonstrated by the Examiner's references, readily enable the full breadth of the pending claims. In particular, transforming and expressing recombinant mammalian proteins in insect and mammalian cells is routine and was so at the filing date of the priority document.

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation. MPEP 2164.02

The Examiner does not supply adequate reasons to establish that a person skilled in the art could not use the genus of processes as a whole without undue experimentation in view of the working examples. On the contrary, the Examiner supplies additional evidence of enablement and then rejects claims for lack of working examples corresponding to particular species. This rejection is without explanation for why one of skill would not be able to practice the singled out embodiments or the genus as a whole and is thus legally insufficient.

In addition to legal insufficiency, the Examiner's rejection is factually incorrect. The co-submitted inventor declaration and supporting references prove enablement of the pending claims.

Applicant requests the Examiner withdraw all rejections and remove all objections. In view of the above, applicant believes the pending application is in condition for allowance.

Three month's extension of time to file is requested and the corresponding fee co-submitted. The fee for the co-submitted terminal disclaimer is also subitted with this response. Applicant believes no other fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02682US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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